

AF/IRU

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

James R. Casciani et al.

Serial No.: 10/698,962

Filed: October 30, 2003

For: Pulse Oximeter and Sensor Optimized
for Low Saturation

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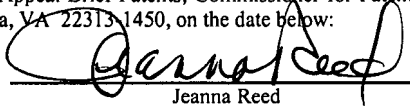
Group Art Unit: 3768

Examiner: Winakur, Eric Frank

Confirmation No: 8826

Atty. Docket: TYHC:0095-3/FLE
009103-009740US

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October 16, 2007	
Date	Jeanna Reed

APPEAL BRIEF PURSUANT TO 37 C.F.R. §§ 41.31 AND 41.37

This Appeal Brief is being filed in furtherance to the Notice of Appeal mailed on August 17, 2007, and received by the Patent Office on August 22, 2007.

The Commissioner is authorized to charge the requisite fee of \$510.00, and any additional fees which may be necessary to advance prosecution of the present application, to Account No. 06-1315, Order No. TYHC:0095-3.

1. **REAL PARTY IN INTEREST**

The real party in interest is Nellcor Puritan Bennett Incorporated by virtue of the Assignment recorded at reel 007833, frame 0813, and dated January 22, 1996. Nellcor Puritan Bennett Incorporated legally changed its name to Nellcor Puritan Bennett LLC on December 29, 2006. Accordingly, Nellcor Puritan Bennett LLC, as successor of the

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Assignee of the above-referenced application, will be directly affected by the Board's decision in the pending appeal.

2. **RELATED APPEALS AND INTERFERENCES**

Appellants are unaware of any other appeals or interferences related to this Appeal. The undersigned is Appellants' legal representative in this Appeal.

3. **STATUS OF CLAIMS**

Claims 72-75 and 84-87 are currently pending. Claims 73-75 and 85-87 are currently withdrawn. Claims 1-71, 76-83 and 88-95 are canceled. Claims 72 and 84 are currently under rejection and are the subject of this Appeal.

4. **STATUS OF AMENDMENTS**

There are no outstanding amendments to be considered by the Board.

5. **SUMMARY OF CLAIMED SUBJECT MATTER**

The application includes two independent claims, namely, claims 72 and 84, all of which are the subject of this Appeal. The subject matter of these claims is summarized below.

With regard to the aspect of the invention set forth in independent claim 72, discussions of the recited features of claim 72 can be found at least in the below cited locations of the specification and drawings. By way of example, present embodiments include emitting light from at least one light source (e.g. light source 210), detecting a plurality of light spectrums from the light with at least one detector (e.g. detector 214) subsequent to the light being scatter by tissue (e.g. patient 212), the plurality of light spectrums including a first light spectrum having a wavelength between 725 and 745 nanometers and a second light spectrum having a wavelength between 880 and 940. *See, e.g., Application, page 10, lines 9-26; FIG. 27.* Further, present embodiments include

calculating a blood oxygen saturation reading based on the plurality of detected light spectrums. *See, e.g.*, Application, page 11, lines 1-13.

With regard to the aspect of the invention set forth in independent claim 84, discussions of the recited features of claim 84 can be found at least in the below cited locations of the specification and drawings. By way of example, present embodiments include emitting a first light (e.g. via light source 210), the first light having a wavelength between 725 and 745 nanometers and emitting a second light (e.g. via light source 210), the second light having a wavelength between 880 and 940 nanometers. *See, e.g.*, Application, page 10, lines 9-11; FIG. 27. Further, present embodiments include detecting the first light with a detector (e.g. detector 214) subsequent to the first light being scattered by tissue (e.g. patient 212) and detecting the second light with the detector (e.g. detector 214) subsequent to the second light being scattered by tissue (e.g. patient 212). *See, e.g.*, Application, page 10, lines 9-14; FIG. 27. Additionally, present embodiments include calculating a blood oxygen saturation reading based on the detected first light and the detected second light. *See, e.g.*, Application, page 11, lines 1-13.

6. **GROUND OF REJECTION TO BE REVIEWED ON APPEAL**

Appellants respectfully urge the Board to review and reverse the Examiner's rejection of claims 72 and 84 under 35 U.S.C. § 103(a) as being unpatentable over Lewis, et al., U.S. Patent No. 5,902,235 (hereafter "the Lewis reference"), in view of Baker et al., U.S. Patent No. 5,431,159 (hereafter "the Baker reference").

7. **ARGUMENT**

As discussed in detail below, the Examiner has improperly rejected the pending claims. Further, the Examiner has misapplied binding legal precedents and principles in rejecting the claims under 35 U.S.C. §103. Accordingly, Appellants respectfully request full and favorable consideration by the Board, as Appellants strongly believe that claims 72 and 84 are currently in condition for allowance.

As set forth above, in the Office Action mailed on May 17, 2007, the Examiner rejected claims 72 and 84 under 35 U.S.C. § 103(a) as being unpatentable over the Lewis reference in view of the Baker reference. Specifically, the Examiner maintained a rejection of claims 72 and 84 under 35 U.S.C. § 103(a) that was previously issued by the Examiner in the Office Action mailed October 16, 2006. In the previous rejection, the Examiner stated the following:

5. Claims 72 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al. (USPN 5,902,235 - previously cited) in view of Baker et al. Lewis et al. teach an oximeter that emits and detects light at measurement wavelengths including 735 nm and at a reference wavelength at 805 nm (a known isobestic point for oximetry measurements). Thus, Lewis et al. teach all of the features of the claimed invention except that light between 880 and 940 nm is emitted and detected. Baker et al. teach 880 nm light is a suitable wavelength for performing the isobestic measurement in an oximeter arrangement (column 7, lines 61 - 66). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Lewis et al. to measure at 880 nm instead of 805 nm, since Baker et al. teach that this is an alternate wavelength to perform an isobestic measurement in an oximeter, and it has generally been held to be within the skill level of the art to substitute alternate equivalent expedients.

Office Action mailed October 16, 2006, page 3.

Appellants respectfully traverse this rejection. The burden of establishing a *prima facie* case of obviousness falls on the Examiner. *Ex parte Wolters and Kuypers*, 214 U.S.P.Q. 735 (PTO Bd. App. 1979). Traditionally, to establish a *prima facie* case of obviousness, the C.C.P.A. and the Federal Circuit have required that the prior art not only include all of the claimed elements, but also some teaching, suggestion, or motivation to combine the known elements in the same manner set forth in the claim at issue. *See, e.g., ASC Hospital Systems Inc. v. Montifiore Hospital*, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984) (holding that obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention absent some teaching or suggestion supporting the combination.); *In re Mills*, 16 U.S.P.Q.2d 1430, 1433 (Fed. Cir. 1990) (holding that

the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination). In *KSR International Co. v. Teleflex Inc.*, No. 04-1350 (April 30, 2007), the court noted that the demonstration of a teaching, suggestion, or motivation to combine provides a “helpful insight” in determining whether claimed subject matter is obvious. *KSR, slip op.* at 14. However, the court rejected a *rigid* application of the “TSM” test. *Id.* at 11. In this regard, the court stated:

The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and explicit content of issued patents. The diversity of inventive pursuit and of modern technology counsels against limiting the analysis in this way. In many fields it may be that there is little discussion of obvious techniques or combinations, and it often may be the case that market demand, rather than scientific literature, will drive design trends. *Id.* at 15.

In other words, the *KSR* court rejected a rigid application of the TSM test which requires that a teaching, suggestion or motivation to combine elements in a particular manner must be explicitly found in the cited prior art. Instead, the *KSR* court favored a more expansive view of the sources of evidence that may be considered in determining an apparent reason to combine known elements by stating:

Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art all in order to determine whether there was an apparent reason to combine in the known elements in the fashion claimed in the patent at issue. *Id.* at 14.

In *KSR*, the Court reaffirmed that “a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *Id.* at 14. In this regard, the *KSR* court stated that “it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does ... because inventions in most, if not all, instances rely upon building blocks long since

uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” *Id.* at 14-15. However, it is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 U.S.P.Q. 769, 779 (Fed. Cir. 1983); M.P.E.P. § 2145. Moreover, if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (C.C.P.A. 1959); *see* M.P.E.P. § 2143.01(VI). If the proposed modification or combination would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984); *see* M.P.E.P. § 2143.01(V).

As quoted above, the Examiner’s rejection of independent claims 72 and 84 is predicated on the combination of the Lewis reference and the Baker reference. However, the Lewis reference explicitly *teaches away* from the combination suggested by the Examiner. Specifically, Baker is directed to non-invasive pulse oximeters and Lewis explicitly teaches away from such pulse oximeters. Further, Baker relates to measuring pulsative characteristics, while Lewis relates to measuring venous characteristics. Appellants respectfully stress that with regard to these arguments, a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

Appellants assert that Baker is directed to pulse oximetry and that Lewis teaches away from pulse oximetry. Support for this assertion can easily be found in the respective references. For example, the following statement from the “Field of the Invention” section of Baker clearly indicates that Baker relates to pulse oximeters:

This invention relates to non-invasive oximetry of the pulse type in which light, which has irradiated a volume of arterial blood within a

subject, is sensed in order to determine oxygen saturation of the subject's blood.

Baker et al. col. 1, lines 9-12 (emphasis added).

Lewis, on the other hand, clearly indicates that combining the invention described by Lewis with a pulse oximeter, such as that described by Baker, would be inappropriate.

For example, Lewis states the following:

[A]rterial pulse oximeter and blood pressure monitors, etc., ... do not provide accurate, ongoing, timely (instantaneous) information as to cerebral (brain) blood oxygenation state, particularly since the brain blood supply is extensive, diffuse, pervasive, and largely *venous rather than arterial. Of course, it is also thus devoid of conventional pulsative characteristics essential to the operation of conventional oximeters.*

Accordingly, *such devices are not appropriate for cerebral usage*, and of course they are typically made to be applied only to peripheral tissue or appendages in any event, i.e., a finger or ear lobe, *and are not utilized in conjunction with venous blood.*

Lewis et al., col. 2, lines 44-58 (emphasis added).

As clearly demonstrated by the quoted passage above, Lewis teaches away from monitors that utilize pulsative characteristics. Indeed, Lewis explicitly lists oximeters that utilize pulsative characteristics as among the devices that are *not* appropriate for the functions and purposes of the invention set forth by Lewis. Thus, the pulse oximeter described by Baker is clearly within the group of devices from which Lewis teaches away. Accordingly, Appellants assert that the theoretical combination of Lewis and Baker, as suggested by the Examiner, is completely inappropriate.

In the "Response to Arguments" section of the Final Office Action mailed May 17, 2007, the Examiner stated that the arguments set forth above were unpersuasive because the "teachings of the references suggest the claimed invention." To support this argument, the Examiner stated the following:

Contrary to Applicant's assertions, the combination is not inappropriate and the teachings of the references suggest the claimed invention. In particular, the teaching of Baker was merely relied upon to show that 805 nm and 880 nm were known isobestic points of hemoglobin. The interaction of isobestic light with a hemoglobin molecule is not affected by the location in the body where the interaction occurs. That the references ultimately process their detected signals in different manners does not "teach away" from the combination, as Baker was merely relied upon to teach known details of the "physics" of light interacting with hemoglobin. The rejection is thus proper and is hereby maintained.

Office Action mailed May 17, 2007, pages 3-4.

The Examiner appears to be drawing unsupported conclusions about the techniques disclosed in the cited references. The Examiner must provide *objective evidence*, rather than subjective belief and unknown authority, of the requisite motivation or suggestion to combine or modify the cited references. *In re Lee*, 61 U.S.P.Q.2d. 1430 (Fed. Cir. 2002).

Turning to the Examiner's specific unsupported assertions, the 880 nm wavelength disclosed in Baker is not an isobestic point as suggested by the Examiner. As stated in Baker, the 880 nm wavelength is used because "[t]his wavelength is close enough to being isobestic that using the isobestic form of equation (1) in the practice of our invention provides satisfactory accuracy." Baker, col. 7, lines 61-66. Thus, 880 nm is clearly not an isobestic point. Further, as stated in Lewis, "[s]ince the specific point at which isobestic conditions exist may vary somewhat as a result of a number of factors, the reference wavelength is *preferably* selected to be at approximately 805 nm." Lewis, col. 7, lines 15-18. It is clear from the discussion in Baker and Lewis that the selection of the wavelength for use in the oximetry techniques respectively disclosed therein is dependent on a number of factors, and the isobestic point simply provides a known data point to be considered in such selection. The Examiner's explanation for the combination of the cited references appears to solely rest on the statement that "[t]he interaction of isobestic light with a hemoglobin molecule is not affected by the location in the body where the interaction occurs." Office Action mailed May 17, 2007, page 4. However,

such a statement is not disclosed in the Lewis reference or the Baker reference, and the Examiner has provided no support for this assertion. Regardless of whether the statement by the Examiner is correct, with the understanding that the Baker reference states it is *not* using an isobestic wavelength, such a statement does not appear to be relevant to the obviousness analysis and does not support combination of the cited references.

The Examiner's insistence that one skilled in the art could simply combine the Lewis reference and the Baker reference is unsupported in light of the fact that the Lewis reference teaches away from pulse oximeters and the Lewis reference *prefers* a wavelength of 805 nm at the isobestic point of hemoglobin. In contrast, Baker clearly discloses *a pulse oximeter* and chooses a wavelength *outside of the isobestic point* of hemoglobin. Thus, Appellants respectfully assert that the Examiner's theoretical combination of the Baker reference and the Lewis reference is inappropriate and unsupported by the teachings in both the Lewis reference and the Baker reference. Indeed, the combination suggested by the Examiner flies in the face of years of well-established legal precedent regarding references that "teach away" from one another.

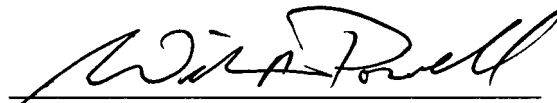
In view of the remarks set forth above, Appellants respectfully submit that the Examiner has not satisfied his burden of establishing a *prima facie* case that claims 74 and 82 are obvious in view of the cited references. For at least these reasons among others, Appellants respectfully request that the Board overturn the rejections under 35 U.S.C. § 103(a).

Conclusion

Appellants respectfully submit that all pending claims are in condition for allowance. However, if the Examiner or Board wishes to resolve any other issues by way of a telephone conference, the Examiner or Board is kindly invited to contact the undersigned attorney at the telephone number indicated below.

Respectfully submitted,

Date: October 16, 2007

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W. Allen Powell

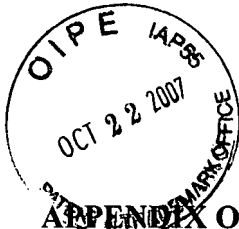
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8. **APPENDIX OF CLAIMS ON APPEAL**

Listing of Claims:

72. A method for measuring blood oxygen saturation comprising:

emitting light from at least one light source;

detecting a plurality of light spectrums from the light with at least one detector subsequent to the light being scattered by tissue, the plurality of light spectrums including a first light spectrum having a wavelength between 725 and 745 nanometers and a second light spectrum having a wavelength between 880 and 940 nanometers; and

calculating a blood oxygen saturation reading based on the plurality of detected light spectrums.

84. A method for measuring blood oxygen saturation comprising:

emitting a first light, the first light having a wavelength between 725 and 745 nanometers;

emitting a second light, the second light having a wavelength between 880 and 940 nanometers;

detecting the first light with a detector subsequent to the first light being scattered by tissue; and

detecting the second light with the detector subsequent to the second light being scattered by the tissue; and

calculating a blood oxygen saturation reading based on the detected first light and the detected second light.

9. **EVIDENCE APPENDIX**

None.

10. **RELATED PROCEEDINGS APPENDIX**

None.